

LETTER FROM THE COMMISSIONER



I am pleased to present the FY 2016 Food and Drug Administration (FDA) Budget.

FDA fulfills its important mission to promote and protect health in an increasingly complex and globalized world in many ways. The scope of our work includes assuring that foods are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, vaccines and other biological products, and medical devices intended for human use are safe and effective; and regulating tobacco products. We also play a lead role in protecting the public from electronic product radiation and assuring that cosmetics and dietary supplements are safe and properly labeled. Finally, we have devoted – and will continue to devote – substantial resources to advancing the public health by helping to speed product innovations.

FDA's responsibilities continue to expand as we work to fulfill the mandates of groundbreaking legislation passed in recent years, including the Family Smoking Prevention and Tobacco Control Act of 2009, the Patient Protection and Affordable Care Act of 2010, the Food Safety Modernization Act (FSMA) of 2011, the FDA Safety and Innovation Act (FDASIA) of 2012, and the Drug Quality and Security Act of 2013. Further, with so many FDA-regulated products manufactured in whole or in part outside of our borders, FDA is keenly focused on the complexities of regulating in a global marketplace.

In FY 2014, we took important steps to finalize a key set of proposed food safety rules; worked to improve the safety of compounded pharmaceutical products by conducting more than 90 inspections and implementing compounding legislation through proposed regulations, guidances, and other actions; published the “deeming rule” to extend FDA’s tobacco authority; and collaborated with federal, international, and industry partners to expedite the development and availability of medical products. In addition, FDA has worked intensively to respond to the Ebola epidemic in West Africa by facilitating the development and availability of investigational diagnostics, therapeutics, and vaccines with the potential to help combat the epidemic.

FDA continues to seek new ways to obtain the most public health value for the federal dollar as we implement expanded authorities. The products that FDA regulates are essential to public health, safety, and quality of life and represent over 20 cents of every consumer dollar spent on products in the United States. Yet, in terms of our FDA budget, each American taxpayer contributes approximately \$8 per year for the vast array of protections and services provided by FDA.

In FY 2016, we are requesting essential and timely resources to address critical food and medical product safety issues. Mindful of the fiscal environment, we have identified targeted reductions where possible and identified long-term needs for additional user fees to balance budget authority growth. FDA is requesting a total of \$4.9 billion to support our various mandates to protect the American people. This includes a \$148 million budget authority increase to focus on the following:

- delivering a farm-to-table system of prevention, including improved oversight of imported foods, through effectively implementing the final rules required by FSMA;
- combating the growing threat of antibiotic resistance – in which drugs become less effective, or ineffective, against harmful bacteria;
- promoting the development and appropriate use of reliable molecular and genetic diagnostics – precision medicine tools – to “personalize” the diagnosis, treatment, and prevention of disease;
- implementing key FDASIA requirements to improve medical product review and inspections;
- addressing the safety of compounded drugs;
- continuing implementation of new requirements for review of sunscreen ingredients under the Sunscreen Innovation Act; and
- supporting modern facilities to provide the laboratories and office space needed to meet FDA’s expanded legislative mandates.

As a science-based regulatory agency with a public health mission, FDA plays a unique and essential role in promoting and protecting public health and safety. We are committed to meeting the needs and expectations of the American people.

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs